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## **REMARKS**

This is in response to the Office Action mailed on <u>January 14, 2004</u>, and the references cited therewith.

Claims 1-9, 11, and 24-48 have been previously canceled, as a result, claims 10, 11-23 and 49-54 are now pending in this application. No new subject matter is added.

## Information Disclosure Statement

Applicant submitted an Information Disclosure Statement and a 1449 Form on August 19, 2003. Applicant respectfully requests that initialed copies of the 1449 Forms be returned to Applicants' Representatives to indicate that the cited references have been considered by the Examiner.

## §112 Rejection of the Claims

Claims 10, 12-23 and 49-54 were rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner alleges that the term "an amino acid ester of  $(\omega$ -(HO)(C<sub>2</sub>-C<sub>4</sub>))alkoxy, N(R<sup>8</sup>)CH(R<sup>8</sup>)CO<sub>2</sub>H, 1'-D-glucuronyloxy, or OCH<sub>2</sub>CH<sub>2</sub>N(CH<sub>3</sub>)<sub>3</sub><sup>+</sup>;" is indefinite, because the groups  $(\omega$ -(HO)(C<sub>2</sub>-C<sub>4</sub>))alkoxy, and OCH<sub>2</sub>CH<sub>2</sub>N(CH<sub>3</sub>)<sub>3</sub><sup>+</sup> are not amino acid esters. This rejection is respectfully traversed.

Applicants note that the term "an amino acid ester of  $(\omega$ -(HO)(C<sub>2</sub>-C<sub>4</sub>))alkoxy" refers to a group having the formula (HO)(C<sub>2</sub>-C<sub>4</sub>))-O- where the hydroxy group is on the terminal position and has had the hydrogen removed and substituted for by an amino acid ester. The amino acid does not refer to the N(R<sup>8</sup>)CH(R<sup>8</sup>)CO<sub>2</sub>H, 1'-D-glucuronyloxy, or OCH<sub>2</sub>CH<sub>2</sub>N(CH<sub>3</sub>)<sub>3</sub><sup>+</sup>; groups. Accordingly, it is respectfully requested that the rejection under 35 USC § 112, second paragraph be withdrawn.

Claims 10, 12-23 and 49-54 were rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner asserted that

allegedly the claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed.

Applicants believe that the law does not require exemplification of the invention. However, in order to expedite the prosecution and gain allowance applicants provide a declaration under 37 C.F.R. § 1.312 from inventors Dennis Carson and Howard Cottam providing evidence that the invention will function as claimed.

In the declaration, data is provided that prove the efficacy of the claimed compounds. Compounds were screened for CLL apoptotic activity by flow cytometry and a MTT-based assay. In addition the compounds were tested using two cell lines LnCap and RPMI8226. The data indicating that the compounds are efficacious are included in the attached Appendix. Applicants respectfully submit that, based on the data provided, a person skilled in the art would be lead to the conclusion that the compounds of the claims have the activity claimed.

In addition, it is noted that the starting materials for preparing the compounds of the invention can be prepared using compounds and methods disclosed in Demerson, U.S. Patent 3,843,681. A reduction of the acids or esters of Demerson provide a functional group (alcohol).

The compounds of the invention can be prepared following the procedures disclosed in the documents in the specification (cited at page 9, lines 9-14). These documents provide procedures that can be used to prepare the compounds of the claims. Thus, the compounds of the invention having the –Y-Z groups of the claims can then be readily prepared using routine transformations and techniques that are well known to a chemist having ordinary skill in the art, starting with the alcohol compound prepared from the reduction of the Demerson acids or esters. These transformations are routinely carried out by a chemist having ordinary skills in organic synthesis. Accordingly, it is respectfully requested that the rejection under 35 USC § 112, first paragraph be withdrawn.

Filing Date: August 9, 2000

Title: INDOLE COMPOUNDS USEFUL FOR THE TREATMENT OF CANCER

## Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6968 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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By their Representatives,

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Date July 19, Jost

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-

1450, on this 14th day of July, 2004.

Name

Signature